

**EXAMINER'S AMENDMENT**

A request for continued examination (RCE) under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 12/27/07 has been entered. Applicant's amendment and response filed concurrently on 12/27/07 has also been entered. Claims 3-4, 8-9, 11, 17, and 19-24 are canceled. Claims 1-2, 5-7, 10, 12-16, and 18 are currently pending in the instant application.

The rejection of previously pending claims 1-2, 5-10 and 12-18 under 35 U.S.C. 112, first paragraph, for scope of enablement, is withdrawn over canceled claims 8-9, and 17, and further withdrawn over amended claims 1-2, 5-7, 10, 12-16, and 18 in view of applicant's amendments to the claims and the examiner's amendment to the claims set forth below, which limit the scope of the claims to that identified in the rejection of record as enabled by the specification.

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Farah on 3/7/08.

The application has been amended as follows:

1. In claim 1, lines 2-3, the phrase " polynucleotide construct" has been replaced by the word -- plasmid-- .

2. In claim 2, line 6, the phrase " polynucleotide construct" has been replaced by the word -- plasmid-- .

3. In claim 10, line 3, the comma “ ,” has been replaced by the word -- or -- ; in line 4, the phrase “ or who has type I diabetes” has been deleted; and in line 6, the phrase " polynucleotide construct" has been replaced by the word -- plasmid-- .

4. In claim 15, line 2, the word -- to -- has been inserted between the words "predisposition" and "type".

Following entry of this examiner's amendment, claims 1-2, 5-7, 10, 12-16, and 18 are considered free of the prior art of record and allowed.

The following is an examiner's statement of reasons for allowance: it is noted that obviousness-type double patenting does not apply between the instant claims and claims 1-3 of

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U.S. Patent No. 6,995,147, hereafter referred to as the '147 patent, because while the claims of the '147 patent recite a broad method for delaying the onset of diabetes comprising intramuscular administration of a plasmid vector encoding a secreted form of human glutamic acid decarboxylase comprising SEQ ID NO:3 under the control of a CMV promoter, the '147 patent does not teach or suggest in either the claims or specification to combine the expression of sGAD55 and Bax for inhibiting the development of type 1 diabetes. Further, the prior art of record does provide any teachings or motivation for this combination.

Any inquiry concerning this communication from the examiner should be directed to Anne Marie S. Wehbé, Ph.D., whose telephone number is (571) 272-0737. If the examiner is not available, the examiner's supervisor, Joseph Woitach, can be reached at (571) 272-0739. For all official communications, **the new technology center fax number is (571) 273-8300**. Please note that all official communications and responses sent by fax must be directed to the technology center fax number. For informal, non-official communications only, the examiner's direct fax number is (571) 273-0737. For any inquiry of a general nature, please call (571) 272-0547.

The applicant can also consult the USPTO's Patent Application Information Retrieval system (PAIR) on the internet for patent application status and history information, and for electronic images of applications. For questions or problems related to PAIR, please call the USPTO Patent Electronic Business Center (Patent EBC) toll free at 1-866-217-9197. Representatives are available daily from 6am to midnight (EST). When calling please have your

application serial number or patent number available. For all other customer support, please call the USPTO call center (UCC) at 1-800-786-9199.

Dr. A.M.S. Wehbé

*/Anne Marie S. Wehbé/  
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